UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FRANCES MOODY,

Plaintiff, **16-CV-901V(Sr)**

v.

ALLERGAN USA, INC.,

Defendant.

REPORT, RECOMMENDATION AND ORDER

This case was referred to the undersigned by the Hon. Lawrence J. Vilardo, pursuant to 28 U.S.C. § 636(b)(1), for all pretrial matters and to hear and report upon dispositive motions. Dkt. #4.

Currently before the Court is defendant's motion to dismiss the complaint. Dkt. #3. For the following reasons, it is recommended that the motion be granted.

BACKGROUND

Defendant received pre-market approval ("PMA"), for the LAP-BAND Adjustable Gastric Banding System ("LAP-BAND"), a class III device intended for use in weight reduction, from the United States Food and Drug Administration ("FDA"), in 2001. Dkt. #3-2. The PMA conditions included approved labeling and advertisement restrictions, as well as requirements for supplementation before making any change affecting the safety or effectiveness of the device and post-approval reports. Dkt. #3-2.

The PMA, as well as the FDA's Summary of Safety and Effectiveness Data for the LAP-BAND, are publicly available on the FDA's website. Dkt. #3-1.

On February 7, 2011, plaintiff underwent laparoscopic surgery to implant a LAP-BAND. Dkt. #1-1, ¶ 13. On April 17, 2014, the LAP-BAND was surgically removed due to slippage and a gastric perforation of the stomach was repaired. Dkt. #1-1, ¶ 19. Plaintiff claims to have suffered substantial pain and suffering, loss of enjoyment of life and emotional distress. Dkt. #1-1, ¶ 21.

Plaintiff commenced this action in the New York State Supreme Court, County of Niagara, on October 13, 2016, alleging the following causes of action:

1. negligence;
2. manufacturing defect;
3. design defect;
4. lack of adequate warning;
5. breach of express warranty;
6. breach of implied warranty of merchantability;
7. breach of implied warranty of fitness for a particular purpose; and
8. violation of New York General Business Law §§ 349 and 350-e.

Dkt. #1-1.

Defendant removed the action to this Court on November 9, 2016 based upon diversity of citizenship. Dkt. #1. On November 16, 2016, defendant moved to dismiss the complaint for failure to state a claim, arguing, *inter alia*, that plaintiff's

common law claims are preempted by the Medical Device Amendments of 1976 ("MDA"). Dkt. #3-4.

Plaintiff responded that the second cause of action alleging a manufacturing defect and the eighth cause of action alleging deceptive trade practices set forth a parallel claim which is not subject to preemption. Dkt. #9.

Defendant replies that these claims fail to allege sufficient factual allegations to state a plausible parallel claim and are, therefore, preempted. Dkt. #10.

At oral argument, plaintiff's counsel confirmed that it was not challenging preemption of the first and third through seventh causes of action and suggested that the complaint might need amendment to allege a sufficient factual basis for the second and eighth causes of action. Dkt. #11. The Court invited plaintiff to file a motion to amend if plaintiff had additional factual allegations to support the second and eighth causes of action. Dkt. #11.

DISCUSSION AND ANALYSIS

Standard of Review

To survive a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), *quoting Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the

court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Application of this standard is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. at 679.

Evidentiary Standard

"In adjudicating a Rule 12(b)(6) motion, a district court must confine its consideration "to facts stated on the face of the complaint or incorporated in the complaint by reference, and to matters of which judicial notice may be taken." *Leonard F. v. Israel Disc. Bank of N.Y.*, 199 F.3d 99, 107 (2d Cir. 1999); *see also Kramer v. Time Warner, Inc*., 937 F.2d 767, 773 (2d Cir. 1991). "Where a plaintiff has relied on the terms and effect of a document in drafting the complaint and that document is thus integral to the complaint," the district court may consider the contents of the document "even if it is not formally incorporated by reference." *Broder v. Cablevision Sys. Corp*., 418 F.3d 187, 196 (2d Cir. 2005) (internal quotations omitted), *quoting Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002). "If the documents referenced in the complaint contradict the facts alleged by the plaintiff, the documents control and the court need not accept as true the plaintiff's allegations." *Olin Corp. v. E.I. Dupont De Nemours and Corp.*, No. 05-CV-100S(Sc), 2006 WL 839415, at *1 (W.D.N.Y. March 27, 2006). A district court may take judicial notice of public documents issued by government agencies such as the Food and Drug Administration. *In re: Zyprexa Products Liab. Litig.*, 549 F. Supp.2d 496, 501 (E.D.N.Y. 2008); *See Simon v. Smith & Nephew,* 990 F. Supp.2d 395, 401 n.2 (S.D.N.Y. 2013) (taking judicial notice of public records contained on FDA website); *Gale v. Smith & Nephew, Inc.,* 989 F. Supp.2d

243, 246 n.2 (S.D.N.Y. 2013) (same); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp.2d 197, 201 n.3 (W.D.N.Y. 2011) (taking judicial notice of FDA's approval letter relative to the PMA application for a class III device).

MDA Preemption

The Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the MDA, "imposed a regime of detailed federal oversight" over the introduction of new medical devices, including an express preemption provision which provides, in relevant part, that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement - (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). Thus, state law claims are preempted when (a) the federal government has established specific requirements applicable to the device and (b) the state law claims are based on requirements that are different from, or in addition to, the federal ones and relate to the safety and effectiveness of the device. *Riegel v. Medtronic,* 552 U.S. 312, 321-22 (2008).

Class III medical devices such as the LAP-BAND at issue in this action are subject to "a rigorous regime of premarket approval," unless the FDA finds the device to be "substantially equivalent" to another device exempt from PMA, in which case the device may enter the market pursuant to the process set forth in 21 U.S.C. § 510k. *Id.* at 317. The FDA grants PMA only if it finds that there is a reasonable

assurance of the device's safety and effectiveness after weighing the probable benefit to health from the use of the device against any probable risk of injury or illness from such use. *Id.* at 318, *citing* 21 U.S.C. § 360e(d) & 21 U.S.C. § 360c(a)(2)(C). Before granting PMA, the FDA must determine that the proposed labeling is neither false nor misleading and may condition approval on adherence to performance standards. *Id.* at 318-19, *citing* 21 U.S.C. § 360e(d)(1)(A) & 21 C.F.R. § 861.1(b)(3). Any changes in design specifications, manufacturing processes or labeling that may affect the safety and effectiveness of a device must be approved in advance by the FDA. *Id.* at 319, *citing* 21 U.S.C. § 360e(d)(6)(A)(I) & 21 C.F.R. § 814.39(c).

Because PMA is tailored to the particular device at issue and is entirely concerned with the safety and effectiveness of the device, the United States Supreme Court has determined that it imposes specific requirements so as to meet the first preemption requirement. *Id.* at 322-23; *See Babayev v. Meditronic, Inc.,* 228 F. Supp.3d 192, 211 (E.D.N.Y. 2017) (PMA "imposes federal, device-specific requirements."). In addition, common law tort claims involving a medical device are premised on the existence of a legal duty imposed by the state, thereby imposing state requirements that are preempted by the device-specific federal requirements. *Riegal,* 552 U.S. at 323-25; *See Babayev*, 228 F. Supp.3d at 212 ("common-law causes of action. . . impose 'requirements' as that term is used in section 360k.").

In *Riegel*, the United States Supreme Court upheld the determination of the Court of Appeals for the Second Circuit that strict liability, negligence, and breach of implied warranty claims under New York common law are expressly preempted by the

MDA. 552 U.S. at 320-21. District courts have also determined that breach of express warranty claims under New York law are expressly preempted by the MDA. *Desabio*, 817 F. Supp.2d at 205; *Horowitz v. Stryker Corp.,* 613 F. Supp.2d 271, 285 (E.D.N.Y. 2009). Similarly, design defect claims, which necessarily challenge the FDA's findings regarding the safety of the device's design, and failure to warn claims, which necessarily challenge a warning label specifically approved by the FDA as part of the PMA process, are preempted by the MDA. *Horowitz*, 613 F. Supp.2d at 284 & 287. Accordingly, it is recommended that these common law causes of action, which plaintiff has chosen not to pursue, be dismissed as preempted by the MDA.

Parallel Claims

The preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330; *See Simon*, 990 F. Supp.2d at 402 ("Put more plainly, section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, *i.e*., received PMA approval, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law.") (internal quotations omitted). "To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Desabio*, 817 F. Supp.2d at 204 (internal quotation omitted). It is insufficient to merely allege that a defendant violated FDA regulations. *Babayev*, 228 F. Supp.3d at 215 (collecting cases). "Plaintiffs cannot simply incant the magic words '[defendants] violated the FDA regulations' in order to avoid preemption." *Gelber v. Stryker Corp*., 788 F. Supp.2d 145,

155 (S.D.N.Y. 2011). "Plaintiffs must also allege a link between the failure to comply and the alleged injury." *Desabio,* 817 F. Supp.2d at 204.

Manufacturing Defect

Defendant argues that plaintiff's complaint fails to allege a sufficient factual basis to support a cause of action for a manufacturing defect. Dkt. #10, p.3.

Plaintiff directs the Court to the allegations in her complaint, which she claims are sufficient to set forth a manufacturing defect claim. Dkt. #9, pp. 2-4.

"To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." *Bertini v. Smith & Nephew, Inc*., 8 F. Supp.3d 246, 257 (E.D.N.Y. 2014) (internal quotation omitted). A manufacturing defect claim should be dismissed if plaintiff has not alleged that the particular product implanted into plaintiff had a defect compared to other samples of the product. *Id.; See Reed v. Pfizer, Inc*., 839 F. Supp.2d 571, 577 (E.D.N.Y. 2012).

In *Gelber v. Stryker Corp*., plaintiff set forth a sufficient manufacturing defect claim by alleging that the artificial hip prosthesis was manufactured with manufacturing residuals that exceeded the manufacturer's internal acceptance criteria in violation of 21 U.S.C. § 351(h) and 21 C.F.R. § 820.70(h), and that this error led to

breaks in the lubrication layer of the device, as evidenced by her doctor's discovery, upon removal of the device, of a stripe on the ceramic head component and wear on the ceramic insert. 788 F. Supp.2d at 155. Plaintiff further noted a warning letter from the FDA to the defendant regarding one manufacturing plant and a voluntary recall of devices manufactured in another plaint. *Id.* at 156. The district court determined that, "[b]y pleading the conduct which plaintiffs allege violated the [current good manufacturing practice requirements ("CGMPs")], describing evidence of the alleged violation, and directing plaintiffs to the CGMP requirements generally, plaintiffs have given defendants more than ample notice of the alleged violations of federal law." *Id.*[1] The district court determined that "[i]t is certainly plausible that by violating internal acceptance criteria, this conduct also violated manufacturing specifications set forth in the premarket approval application." 788 F. Supp.2d at 157. Similarly, in *Rosen v. St. Jude Medical, Inc*., the district court determined that plaintiff had set forth a plausible parallel claim for manufacturing defect where plaintiff alleged FDA enforcement actions, defendants' warning letters to doctors regarding defects in insulation and increased abrasion rates for an implantable cardiac defibrillator and a subsequent recall of the device, as well as allegations that, upon removal, the device was fractured and the conductor coils had externalized. 41 F. Supp.3d 170, 181 (N.D.N.Y. 2014).

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[1] The Court notes that alleged violations of CGMPs, standing alone, are insufficient to sustain a parallel claim. *See Sprint Fidelis Leads Litig. II,* 623 F.3d 1200, 1206 (8th Cir. 2010) (claim for manufacturing defect is preempted where plaintiff alleged general failure to comply with CGMPs but failed to allege a violation of a specific federal requirement); *Pearsall v. Medtronics, Inc*., 147 F. Supp.3d 188, 198-99 (E.D.N.Y. 2015) ("CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead a violation of a federal requirement."); *Ilarrazza v. Medtronic, Inc*., 677 F. Supp.2d 582, 588 (E.D.N.Y. 2009) (alleged violations of CGMPs, which are intended to serve only as an umbrella quality system providing general objectives which medical device manufacturers must strive to achieve, are simply too generic, standing alone, to serve as the basis for a manufacturing defect clam).

In the instant case, in contrast, plaintiff alleges nothing more in the way of facts than that defendant "failed to comply with FDA quality system requirements and regulations regarding design control, design, design validation, perfect performance and efficiency, and manufacturing and production standards, pursuant to 21 C.F.R. Sec. 820" (Dkt. #1-1, ¶ 22 (u)), and her second cause of action alleges only that the Lap-Band that was implanted in plaintiff "was defective in its manufacture when it left the hands of Defendant in that it deviated from product specifications, posing a serious risk that it could fail in patients. Dkt. # 1-1, ¶ 36. The complaint fails to suggests the nature of the defect, how such a defect violated the manufacturing standards required by the PMA, or how such a defect contributed to plaintiff's alleged injury. Accordingly, it is recommended that it be dismissed for failure to state a plausible parallel cause of action asserting a manufacturing defect claim. *See Babayev*, 228 F. Supp.3d at 216; *Gelber v. Stryker Corp*., 752 F. Supp.2d 328, 335 (S.D.N.Y. 2010) ("By failing to allege any facts surrounding the defectiveness of the [device] implanted in [plaintiff] or a plausible theory for how the device was manufactured improperly, Plaintiffs do not give Defendants any notice of the basis for their manufacturing defect claim."); *Ilarrazza,* 677 F. Supp.2d at 588 ("Where, as here, the plaintiff has done nothing more than recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed); *Horowitz*, 613 F. Supp.2d at 284 ("Without more specific allegations explaining how defendants' manufacturing process was in violation of federal requirements so that the device was defective, plaintiff's claim falls directly within the MDA's preemption provision.").

New York General Business Law

Defendant argues that plaintiff has failed to allege a sufficient factual basis to support a claim pursuant to New York General Business Law. Dkt. #3-4, p.29.

Plaintiff directs the Court to the allegations in her complaint, which she claims are sufficient to set forth a claim for deceptive trade practices. Dkt. #9, pp. 5-11.

Defendant replies that there is no allegation that plaintiff was subjected to an allegedly deceptive statement, let alone that she relied upon such statement in assessing whether to implant the LAP-BAND. Dkt. #10, p.8.

To establish a claim pursuant to Section 349 of New York's General Business Law, the plaintiff must allege that a defendant is engaging in consumer-oriented conduct which is deceptive or misleading in a material way, and that the plaintiff has been injured as a result. *Horowitz*, at 287. "Deceptive acts are defined as those that are 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *Id., quoting Oswego Laborers' Local 214 Pension Fund*, 85 N.Y.2d 20, 26 (1995). "To properly allege causation, a plaintiff must state in [her] complaint that [she] has seen the misleading statements of which [she] complains before [she] came into possession of the products [she] purchased." *Goldemberg v. Johnson Consumer Cos., Inc.*, 8 F. Supp.3d 467, 480 (S.D.N.Y. 2014).

New York General Business Law § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce." To establish such a claim, a plaintiff

must demonstrate that the advertisement had an impact on consumers at large, was deceptive or misleading in a material way, and resulted in injury. *Horowitz*, 613 F. Supp.2d at 287. To state a claim pursuant to § 350, "a plaintiff must plead reliance on a false advertisement at the time the product was purchased." *Id.* at 288.

The eighth cause of action alleges that defendant "unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Lap-Band as a high-quality, safe, and effective weight loss system to Plaintiff and Plaintiff's physicians" (Dkt. #1-1, ¶ 90), even though defendant "knew that the LAP-BAND subjected patients to failure and severe gastrointestinal damage, painful and harmful physical reactions, and the need for removal, revision, and/or gastrointestinal repair surgery." Dkt. #1-1, ¶ 109. Plaintiff further alleges that defendant engaged in unfair methods of competition or deceptive acts or practices that were proscribed by law, including, representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have advertising goods or services with the intent not to sell them as advertised; and engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding. Dkt. #1-1, ¶ 95.

As an initial matter, the complaint fails to specify a representation made by defendant outside of the confines of the promotional materials explicitly approved as part of the PMA process. *See Horowitz*, at 288 ("using the NYGBL to attack [an] FDA-approved label would run afoul of the MDA's preemption provision."). Furthermore, the complaint fails to allege reliance by plaintiff on any alleged misrepresentation by defendant during the course of her determination to undergo implantation of the LAP-

BAND, or to allege any link between such misrepresentation and the injury she allegedly caused by the LAP-BAND. As a result, it is recommended that plaintiff's eighth cause of action be dismissed for failure to state a parallel claim pursuant to Fed. R. Civ. P. 12(b)(6).

CONCLUSION

For the foregoing reasons, it is recommended that the defendant's motion to dismiss (Dkt. #3), be granted. In light of plaintiff's failure to move to amend the complaint, despite her counsel's recognition that additional facts might need to be alleged in order to meet the plausibility standard for parallel claims, it is recommended that such dismissal be with prejudice.

Therefore, it is hereby ORDERED pursuant to 28 U.S.C. § 636(b)(1) that:

This Report, Recommendation and Order be filed with the Clerk of the Court.

ANY OBJECTIONS to this Report, Recommendation and Order must be filed with the Clerk of this Court within fourteen (14) days after receipt of a copy of this Report, Recommendation and Order in accordance with the above statute, Fed.R.Civ.P. 72(b) and Local Rule 72(b).

The district judge will ordinarily refuse to consider *de novo* arguments, case law and/or evidentiary material which could have been, but were not presented to the

magistrate judge in the first instance. *See, e.g., Patterson-Leitch Co. v. Massachusetts Mun. Wholesale Electric Co.*, 840 F.2d 985 (1st Cir. 1988).

Failure to file objections within the specified time or to request an extension of such time waives the right to appeal the District Court's Order. *Thomas v. Arn*, 474 U.S. 140, 106 S. Ct. 466, 88 L. Ed.2d 435 (1985); *Wesolek v. Canadair Ltd.*, 838 F.2d 55 (2d Cir. 1988).

The parties are reminded that, pursuant to Rule 72(b) of the Local Rules for the Western District of New York, "written objections shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for such objection and shall be supported by legal authority." Failure to comply with the provisions of Rule 72(b) may result in the District Judge's refusal to consider the objection.

The Clerk is hereby directed to send a copy of this Report, Recommendation and Order to the attorneys for the parties.

SO ORDERED.

DATED: Buffalo, New York
December 5, 2017

s/ H. Kenneth Schroeder, Jr.
H. KENNETH SCHROEDER, JR.
United States Magistrate Judge